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RANGER MEDIC EVALUATION FOR FIELD USE OF A CORE TEMPERATURE MONITORING UNIT

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33. ABSTRACT (Maximum 200 words) Management of heat injuries in military training and combat is a serious issue for military medical personnel. In addition to severe health consequences associated with heat stroke, the financial implications are great. The uses of new clinical tools to help diagnose and treat heat injuries are necessary to minimize the risk of a heat injury. One device that may be useful is a Core Temperature Monitoring (CTM) unit that assesses core temperature through use of a telemetric thermometer pill that transmits core temperature data to a radio receiver. The primary goals of this study were to (a) determine utility of CTM system when used by Ranger Training Brigade (RTB) medics to "spot check" thermal strain of Ranger School students engaged in Ranger training, and (b) obtain a product evaluation of the CTM from the RTB medics, one of the potential customers of the product. Feedback on the acceptability and functionality of the device was provided by nine RTB medics after using the device while overseeing training at the RTB Qualification School. Data were obtained through the use of a 22-item questionnaire. Questions included both open-ended items and those on a 9-point hedonic Likert rating scale. Data were also obtained through the use of small focus groups. This device was primarily used before and after various RTB events. RTB medics rated the device moderately to very easy to use. All subjective ratings of the product were significantly (p < 0.005) more positive than the neutral point on the 9-point Likert-rating scale. All RTB medics stated they were moderately likely to extremely likely to use this product if it were provided to them. Improvements to the system most commonly stated were to have it capture a full set of vital signs and to obtain core temperature readings more quickly. RTB medics would also like to be able to obtain temperature readings when more than a meter away from a patient. Recommended prices for the pills were maximum of \$10.00/telemetric thermometer pill.					
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DISCLAIMERS

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Human subjects participated in these studies after giving their free and informed voluntary consent. Investigators adhered to AR 70-25 and USAMRMC Regulation 70-25 on the use of volunteers in research.

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EXECUTIVE SUMMARY

Management of heat injuries in military training and combat is a serious issue for military medical personnel. In addition to severe health consequences associated with heat stroke, the financial implications are great. It has been estimated that the cost of heat stroke injuries as a result of military training is approximately \$10M/year. The uses of new clinical tools to help diagnose and treat heat injuries are necessary to minimize the risk of a heat injury and the severity if one should occur. One device that may be useful is Mini Mitter Inc.'s (Bend, OR) VitalSense® Core Temperature Monitoring (CTM) unit. This device recently received the Food and Drug Administration's (FDA's) 510k certification for use to assess human core temperature. This CTM unit assesses core temperature through the use of a telemetric thermometer pill that transmits core temperature data to a radio receiver. Objective: The primary goals of this study were to (a) determine the utility of the CTM system when used by Ranger Training Brigade (RTB) medics to "spot check" thermal strain of Ranger School students engaged in Ranger training, and (b) obtain a product evaluation of the CTM from the RTB medics, one of the potential customers of the product. Methods: Feedback on the acceptability and functionality of the device was provided by nine RTB medics after using the device while overseeing training at the RTB Qualification School. Data were obtained through the use of a 22-item questionnaire. Questions included both openended items and those on a 9-point hedonic Likert rating scale. Data were also obtained through the use of small focus groups. This device was primarily used before and after the 5-mile run, 2.5-mile individual equipment run, land navigation course, and 13-mile road march. Results: RTB medics rated the device moderately to very easy to use. All subjective ratings of the product were significantly (p < 0.005) more positive than the neutral point on the 9-point Likert-rating scale. All RTB medics stated they were moderately likely to extremely likely to use this product if it were provided to them. Improvements to the system most commonly stated were to have it capture a full set of vital signs and to obtain core temperature readings more quickly. RTB medics would also like to be able to obtain temperature readings when more than a meter away from a patient. Recommended prices for the pills were a maximum of \$10.00/telemetric thermometer pill, with a suggested price of approximately \$1.00/telemetric thermometer pill. Conclusion: In summary, the CTM device would be acceptable for use by the RTB medic to improve medical diagnosis of heat injuries during Ranger training. At the current cost of \$50/pill, the device would not be adopted despite its obvious utility.

INTRODUCTION

Understanding why hot weather injuries occur, and developing ways to prevent them, are important concerns for the military given the approximately 120 heat stroke injuries that occur per year among Warfighters, with an associated \$10M/year cost. Heat stroke injury rates can be estimated from the Defense Medical Epidemiological Database (DMED) (http://amsa.army.mil) for a population of about 1.4 million Warfighters from all services. Over the past 10 years, there have been about 878 heat stroke injuries, with the majority from the US Army (511) and Marine Corps (300). Current estimated cost per affected Soldier is \$132,000, based on duty days lost, and the costs of hospitalization, replacement, and disability. Clearly, efforts to develop new ways to manage thermal strain and reduce heat casualty rates are warranted.

The severity of heat injury is related to the magnitude and duration of excessive core temperature elevation, although the relationship is not precise. Having the ability to measure and monitor core temperature in field situations could help prevent heat stroke and improve the clinical assessment and treatment of heat casualties. Generally, if core temperature can be maintained below 39.5 to 40 °C the risk of becoming a serious heat casualty is minimized. However, less serious heat exhaustion may occur at lower core temperatures. Monitoring individual core temperature during strenuous high-risk activities should be very effective in preventing most but not all heat casualties (Heat Stress Control and Heat Casualty Management; Draft TB MED 507/AFHNBK 48-152).

Classically, core temperature is measured by rectal or esophageal probes (8). Fortunately, an equally valid but much less obtrusive method exists for measuring core temperature – the ingested telemetric thermometer pill. Anomalous temperature readings due to the ingestion of water can occur during the 1 to 2 hours that the pill is in the stomach (9). These temperature excursions have a characteristic shape (4) and can be readily identified. When the temperature pill is used as a diagnostic tool, RTB medics must be aware that in the 2 or 3 hours after pill ingestion, core temperature measurements may be transiently affected by the consumption of hot or cold fluids. Accurate core temperature readings may be provided when the temperature of the fluid equilibrates to body temperature. This occurs within about 1 to 4 minutes, depending on the volume and temperature of the bolus of fluid consumed. The telemetric thermometer pill method otherwise provides valid measurements of core temperature whether during rest, exercise, or conditions when core temperature is rising or falling (4, 7, 10).

The primary goals of this study were to (a) determine the utility of the Core Temperature Monitoring (CTM) system when used by Ranger Training Brigade (RTB) medics to "spot check" thermal strain of Ranger School students engaged in Ranger training, and (b) obtain a product evaluation of the CTM from the RTB medics, one of the potential customers of the product.

METHODS

VOLUNTEERS

Nine male RTB medics volunteered for this evaluation. One RTB medic had received his Ranger Tab and one-third (3 of 9) had acquired their Expert Field Medical Badge (EFMB). The average time in service was 7.2 ± 5.1 yrs (minimum: 0.9 yrs, maximum: 13.5 yrs). Prior to data collection, all volunteers were briefed on the purpose, procedures, and known risks of the study and gave their written consent. The U.S. Army Research Institute of Environmental Medicine's Institute Review Board and Scientific Committee approved the study. Volunteers also signed a videotape release permitting the use of their images and sounds for data collection purposes.

EXPERIMENTAL PROCEDURE

RTB medics were trained on the use of the Mini Mitter Inc. (Bend, OR) VitalSense® Thermometer Pill and CTM unit (Figure 1). Volunteers were given a chance to use the CTM unit while monitoring students during the Rapid Assessment Phase (RAP) of Ranger Training. Use of the CTM to obtain core temperatures was done before and after four events: the 5-mile run, the individual 2.5-mile equipment run, land navigation, and a 13-mile road march. At the end of 7 days of training using the CTM during key events, volunteers completed a brief survey and participated in a focus group session to obtain subjective feedback on the use of the CTM system.

<u>Survey</u>

RTB medics were administered a 22-item survey (Appendix A) to obtain a brief amount of background information and to assess the importance of knowing a Soldier's core temperature while treating them during Ranger training. In addition, questions regarding the acceptability and functionality of the Mini Mitter Inc. VitalSense® system were obtained. The survey asked general questions about the Mini Mitter Inc. VitalSense® system and was completed before the more specific and group responses were obtained in the focus group sessions.

Focus Group

RTB medics who used the CTM during Ranger training subsequently participated in focus groups to discuss the value of the CTM and how the system might be improved.

Figure 1. Mini Mitter Inc. VitalSense® Core Temperature Monitoring unit and telemetric thermometer pill (a patch for monitoring skin temperature, which was not used, is also shown)



Three groups were interviewed: one group with five volunteers, one with three volunteers, and the final volunteer was interviewed alone. The RTB medic that was interviewed individually had missed the scheduled interview session because of mission essential medical duties. Focus groups with less than seven participants are consistent with standard practice (3). The focus groups were presided over by a USARIEM moderator who had no financial or professional stake in the evaluation outcome of this product. The moderator followed guidelines recommended by Aaker and Day (1) such as not using jargon, making sure all volunteers contributed their ideas, and validating each idea as important. Topics introduced proceeded from general to more specific and followed the general outline by McQuarrie and McIntyre (6). Topics covered included the following questions:

<u>I. Problem/Need Identification</u>. Did you currently have any problems assessing core temperatures? How do you currently assess a Soldier's core temperature? How do you assess core temperature in the field when the Soldier is fully clothed including PPE (personal protective equipment)? Are there at-risk individuals? How do you make this judgment? How are these individuals medically managed during training?

- <u>II. Presentation of Product Concept</u>. The product assesses core temperature through the use of a thermometer pill that is swallowed and sends its signal to a receiver. In general, what do you think about the concept?
- <u>III. Evaluation of Product.</u> What do you think about this particular product? What are the least attractive features? What are the most attractive features?
- <u>IV. Determination of Price Points</u>. If a product like this were available, would you ask for it through your supply chain? How much do you think a device like this should cost? What is a reasonable amount for the Army to pay for each thermometer pill?
- V. Extensions of the Product. Are there other features you would like to see this device possess that it currently does not have? Is there any value in having the thermometer pill CTM receiver be part of a Medic Personal Digital Assistant (PDA)? Would the CTM benefit other military groups more or less than the RTB? Any groups of medical personnel that would not need this technology? Are there civilian uses for this technology?
- VI. Suggestions for Improving the Product. Are there any improvements that are needed?

The focus group sessions were videotaped (5) and the discussion transcribed. Transcriptions of the focus group sessions may be found in Appendix B. All participants were informed that the focus group videotape was being used only for data collection and analysis purposes and not used for other purposes such as part of a scientific presentation, commercial, or news story. Volunteers wore physical training clothing and/or had tape placed over their uniform nametags to assure anonymity. Names were not used during any of the focus group sessions. Positive and negative statements were tabulated and paraphrased to encompass the meaning of similar responses. The categorical responses of these qualitative data were then summarized and presented in table form.

DATA ANALYSIS

Survey data were analyzed using SPSS 12.0 statistical software (SPSS, Inc., Chicago, IL). Frequency of responses and descriptive statistics (mean, median, standard deviation, minimum and maximum) were obtained. For the various subjective ratings using a 9-point Likert scale, one-sample t-tests were employed to determine if the mean rating reported was significantly different than the neutral point of five.

RESULTS

SURVEY

RTB medics responded that knowing a Ranger student's core temperature is very important (n = 1) to extremely important (n = 8) when treating a student. When asked how a patient's temperature would be assessed, all nine RTB medics responded that it would be obtained rectally. Four of the nine RTB medics stated that oral temperatures are also obtained. One mentioned that oral temperatures are obtained when some form of sickness is suspected, while rectal temperatures are obtained for suspected heat injuries. Another RTB medic said that a rectal temperature is taken for any suspected exertion type injury, or if a high oral temperature measurement is obtained.

The mean number of readings obtained by RTB medics with the CTM was 5 ± 8 readings (minimum = 0, maximum = 23). Only one volunteer, the one who took 23 readings, had unacceptable or non-readings. This volunteer had 11 non-readings (47.8%). When asked how quickly they needed to obtain a core temperature reading, RTB medics responded that they needed to obtain them within 5 to 15 seconds (n = 3), within 1 minute (n = 3), or as soon as possible (n = 3). When asked if the CTM was able to obtain a core temperature within the time frame needed to do their job, four RTB medics reported that it was able to meet the time restraint, and three RTB medics reported that it did not meet those time restraints. Two RTB medics left this question blank.

When RTB medics were asked how helpful the CTM and thermometer pill would be in treating Soldiers, all RTB medics agreed that the use of this device would be moderately helpful (n = 1), very helpful (n = 5) or extremely helpful (n = 3). All volunteers believed that if these CTM units were accurate and available to them, their use would be an improvement over the RTB medic's current level of evaluation and diagnosis of a Soldier's core temperature. When asked about the ease of use, acceptability of various attributes of the CTM unit, whether the temperature readings seemed accurate to them, their likelihood of using the CTM on the job if it were available to them, and their overall level of acceptability of the device, most volunteers rated the CTM positively. Figures 2-9 show the frequency distributions of the responses for each question asked. Table 1 summarizes the mean responses. The CTM was rated significantly more positive than the neutral score at the $p \le 0.005$ level of significance for each item.

Figure 2. Frequency of responses for ease of use of the Core Temperature Monitor

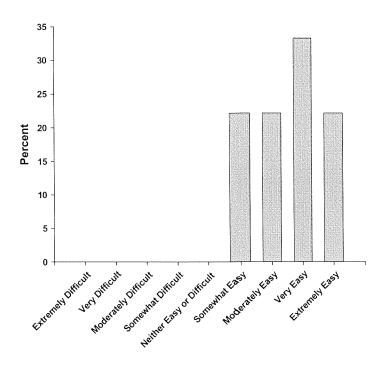


Figure 3. Frequency of responses for ease of use of the Core Temperature Monitor menu function keys

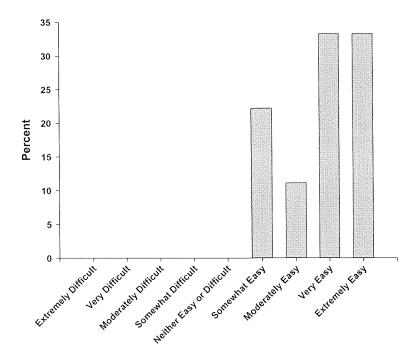


Figure 4. Frequency of responses for acceptability of the Core Temperature Monitor window display

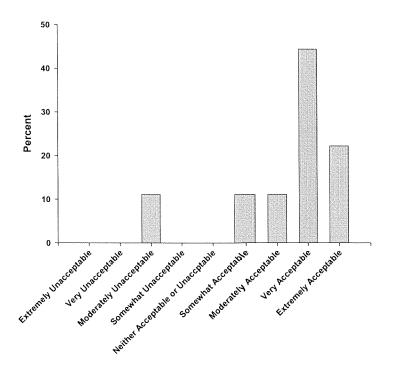


Figure 5. Frequency of responses for acceptability of the size of the Core Temperature Monitor

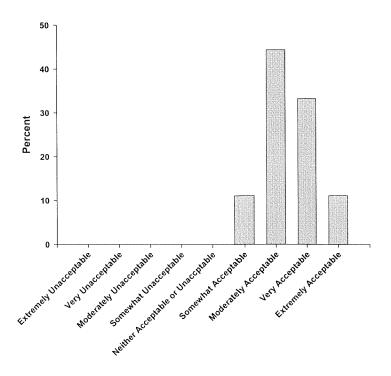


Figure 6. Frequency of responses for acceptability of the weight of the Core Temperature Monitor

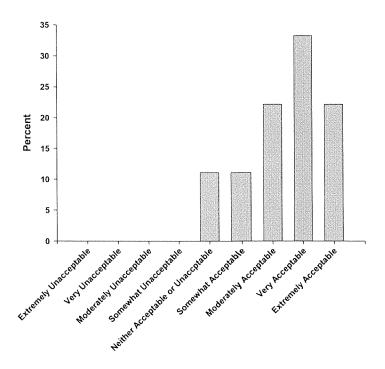


Figure 7. Frequency of responses for accuracy of readings of the Core Temperature Monitor

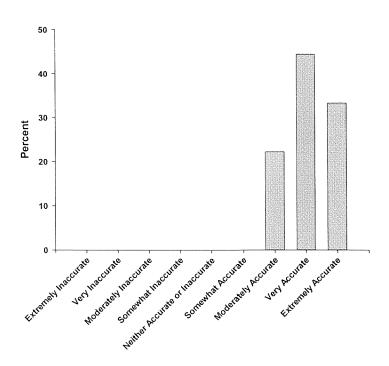


Figure 8. Frequency of responses for likelihood to use the Core Temperature Monitor on the job if it were provided

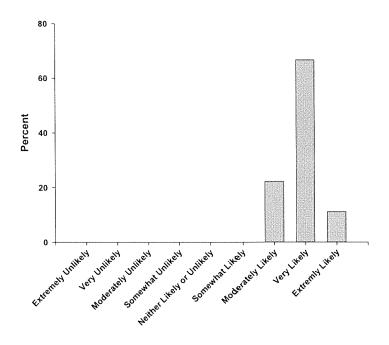


Figure 9. Frequency of responses for overall acceptability of the Core Temperature Monitor

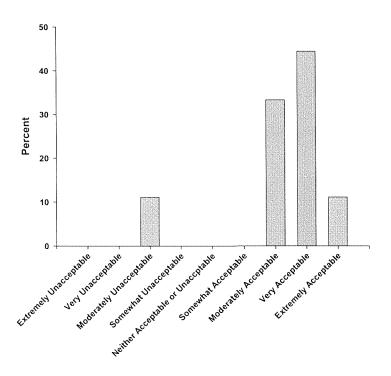


Table 1. Mean Subjective Ratings of the Core Temperature Monitor Unit.

Measure	Mean <u>+</u> S.D.	Median	Minimum	Maximum
CTM easy to use ¹	7.6 <u>+</u> 1.1*	8	6	9
Menu function keys were easy to use ¹	7.8 <u>+</u> 1.2*	8	6	9
Window display was acceptable ²	7.3 <u>+</u> 1.9*	8	3	9
CTM size was acceptable ²	7.4 <u>+</u> 1.9*	8	6	9
CTM weight was acceptable ²	7.4 <u>+</u> 1.3*	8	7	9
Temperature readings seemed accurate (comparing to other signs of the patient) ³	8.1 + 0.8*	8	7	9
	_			
Likely to use CTM on the job ⁴	7.9 <u>+</u> 0.6*	8	7	9
Overall Acceptability ²	7.2 <u>+</u> 1.7*	8	3	9

Anchor scores for the above measures were as follows:

For ease of use questions:

1= Extremely Difficult, 2 = Very Difficult, 3 = Moderately Difficult, 4 = Somewhat Difficult, 5 = Neither Easy nor Difficult, 6 = Somewhat Easy, 7 = Moderately Easy, 8 = Very Easy, 9 = Extremely Easy

For acceptability questions:

1= Extremely Unacceptable, 2 = Very Unacceptable, 3 = Moderately Unacceptable, 4 = Somewhat Unacceptable, 5 = Neither Acceptable nor Unacceptable, 6 = Somewhat Acceptable, 7 = Moderately Acceptable, 8 = Very Acceptable, 9 = Extremely Acceptable

For accuracy question:

1= Extremely Inaccurate, 2 = Very Inaccurate, 3 = Moderately Inaccurate, 4 = Somewhat Inaccurate, 5 = Neither Accurate nor Inaccurate, 6 = Somewhat Accurate, 7 = Moderately Accurate, 8 = Very Accurate, 9 = Extremely Accurate

For likely to use question:

1= Extremely Unlikely, 2 = Very Unlikely, 3 = Moderately Unlikely, 4 = Somewhat Unlikely, 5 = Neither Likely nor Unlikely, 6 = Somewhat Likely, 7 = Moderately Likely, 8 = Very Likely, 9 = Extremely Likely

*Designates measure was significantly greater than the neutral point score of 5 using a one sample t-test at the 0.005 level of significance.

When asked if there are certain Soldiers that are "at risk" whose health status could be maintained by monitoring core temperatures, eight of nine RTB medics agreed that there are "at risk" Soldiers. Risk factors cited include prior hot weather injuries (n = 6), prior cold weather injuries (n = 2), coming from a colder-less humid environment/not acclimated to the environment (n = 2), those who exhibit fatigue or sickness (n = 1), and poor physical fitness (n = 1). When RTB medics were asked if these Soldiers were identified, how would temperature monitoring improve their level of care? Responses included the following:

- By identifying "at risk" students and monitoring them, care could be provided before the Soldier "goes down," thereby keeping Soldiers in training (n = 4).
- Remove these Soldiers from training earlier (n = 2).
- Easier to monitor these Soldiers during potential heat injury scenarios, providing for better evaluation (n = 2).
- Load could be eased somewhat on these Soldiers before they went down (n = 1).
- By having quicker access to vital signs, whatever treatment these Soldiers would normally get, they would get it sooner (n = 1).

FOCUS GROUP

Response to various questions posed by the moderator elicited similar responses from the volunteers and were consistent with the survey data. Sometimes, though, not all individuals responded to every question. Therefore, a non-response does not necessarily mean the RTB medic disagreed with what someone else said; it just means they did not respond. Also, often the same individual would give multiple answers addressing the same issue, accounting for why total values of the responses (summing down a column) in a table exceed 9, the number of volunteers in the study.

Tables 2 and 3 summarize responses of the RTB medics regarding current treatment of heat injuries. RTB medics unanimously (n = 9) agreed that there are certain "at-risk" Soldiers for heat injuries. Risk factors mentioned are presented in Table 4. Risk factors also included certain activities during Ranger School such as the 5-mile run or road march. In addition, it was noted that the continuous nature of the training reduces opportunities for the body to cool off. As students move to other phases of Ranger School beyond RAP week, depending on the weather, the risks during training can increase over those observed during RAP week, because loads being carried increases. However, the risk is moderated as the Ranger students become more acclimated to the heat and their fitness levels improve. Furthermore, many of the more at-risk students may have already been dropped from the class during RAP week for medical or performance reasons.

Table 2. How are Heat Injuries Assessed?

Response	n	% of Total
Strip clothing off of patient to get a rectal temperature	8	99.9
Pull suspected heat-injured patient into ambulance and take a		
set of vitals including core temperature	6	66.7
Establish consciousness of the patient	3	33.3

Table 3. Biggest Obstacle when Dealing with Heat Injuries.

Response	n	% of Total
Getting the first set of vitals in a timely fashion	4	44.4
Getting a patient's clothes off	3	33.3
Getting the patient to the ambulance	3	33.3
Establishing communication with the patient	2	22.2
Communication with other medical personnel	1	11.1
Taking the rectal temperature	1	11.1
Identifying who is having a problem	1	11.1
No problem	1	11.1

Table 4. Heat Injury Risk Factors.

Response	n	% of Total
Not physically conditioned properly	5	55.6
Prior heat injuries	5	55.6
Coming from a cold or cooler environment/unacclimated to the		
heat and humidity	5	55.6
Taking medications and nutritional supplements	2	22.2
Carrying extra body weight (both extra fat and lean body mass)	2	22.2

RTB medic volunteers were first asked about the use of thermometer pill technology, in general, to assess body core temperature. Volunteers were asked if they thought it would be a useful technology, and in general, whether they like the concept of obtaining a core body temperature from a radio-transmitting pill with an associated radio receiver. All volunteers (n = 9) thought that the technology could be useful. Table 5 summarizes the positive and negative comments regarding the usefulness of thermometer pill technology. RTB medic volunteers were then asked what they thought about Mini Mitter Inc.'s VitalSense® thermometer pill system. Table 6 summarizes these positive and negative comments. Improvements to the VitalSense® thermometer pill system that were suggested are listed in Table 7. Putting the system on a PDA might be beneficial, as about a third of those interviewed thought that having less equipment to worry about is always an advantage. Furthermore, the ability to store and download patient data from a PDA device was also recommended.

Table 5. Usefulness of Thermometer Pill Technology.

Response	Ν	% of Total
Positive Comments		
Potentially saves time in getting core temperatures	4	44.4
Good for giving to at-risk individuals to monitor	3	33.3
Good at monitoring individuals' temperature while they are in		
chemical protective clothing that increases core temperatures	3	33.3
Don't need to do medical procedures on a potentially sensitive		
area of the body, the rectum (both in physical and emotional		
terms with respect to the patient)	2	22.2
Can get a temperature while individual is running or participating		
in some other event and get them to slow down before they drop	2	22.2
Can get temperatures in the field where vehicles can't go	2	22.2
It would be a good technology to use in general	2	22.2
Good for evaluating females to avoid privacy issues of male		
medics taking rectal temperatures	1	11.1
Negative Comments		
Pill transit time is too fast	1	11.1

Table 6. Usefulness and Acceptability of the Mini Mitter Inc. VitalSense® Product.

Response	n	% of Total
Positive Comments		
Don't have to take patient's clothes off to get a core temperature	6	66.7
Fast to obtain a temperature reading	3	33.3
Simple and easy to use	2	22.2
Patients would be willing to take the pill	2	22.2
System worked well	2	22.2
Able to monitor multiple patients at once	1	11.1
Compact size of the unit is good	1	11.1
Screen was good	1	11.1
Software was user-friendly	1	11.1
Belt pouch for the Core Temperature Monitor unit was good	1	11.1
It is a good idea	1	11.1
Get temperature in the field and monitor patient while in transit to		
ambulance or aid station	1	11.1
Negative Comments		
Hard to use in the dark	4	44.4
Need to get too close to a person to obtain temperature	3	33.3
Having to give the pill so often because of quick GI transit times	3	33.3
Slow to obtain a temperature reading	3	33.3
Battery life is too short	1	11.1
Getting students to remember to take the pill	1	11.1
Would want to make sure the pill temperature is accurate; i.e.,		
would need to have it demonstrated in a side-by-side		
comparison with a rectal thermometer	1	11.1

Table 7. Improvements to the Mini Mitter Inc. VitalSense® Product.

Response	n	% of Total
Send a patient's data back to the aid station or other places	6	66.7
Be able to program pill number so that it could correspond with a		
Soldier's roster number	5	55.6
Be able to get a complete set of vitals	5	66.6
Be able to point the Core Temperature Monitoring unit at the		
patient and get a temperature immediately	4	44.4
Buttons should be lit	3	33.3
Obtain a signal from farther away from the individual	3	33.3
Stick with the pill, don't use a skin patch; would not work as well	2	22.2
Stronger signal from the pill to the receiver	1	11.1
Improve length of battery life	1	11.1
Flag vital signs with asterisk or auditory sound when in danger		
zone	1	11.1
Speed up recording of temperatures	1	11.1
Improve screen display lighting for use in the dark	1	11.1
Have a light-dark sensor that automatically lights up the screen		
and buttons in low light conditions	1	11.1
Use a skin patch for temperature	1	11.1
Be able to detect hydration state	1	11.1

Basic Training was mentioned by six of the nine RTB medics as another military group that might be able to use this technology. In fact, one RTB medic stated that use of this technology at Basic Training might be even more important than for Ranger Training because there are more "at risk" individuals; i.e., individuals coming into the Army for the first time who are not used to the Army's physical training standards. Also, he said that medical monitoring and the medical facilities are not as advanced at Basic Training at Ft. Benning, GA, as those in place for Ranger Training at Ft. Benning, GA. Table 8 summarizes other military units where temperature monitoring using the CTM might be of use. Table 9 summarizes possible civilian uses mentioned by these RTB medics. A majority of RTB medics (n = 6) mentioned using the CTM for monitoring athletes during hot weather training or competition. Most often stated was the monitoring of football practice during the summer months when heat injuries are often a problem.

Table 8. Other Military Units that Might be able to use the Mini Mitter Inc. VitalSense® Product.

Response	n	% of Total
Basic Training	6	66.7
Deployed Soldiers	3	33.3
Ranger units	2	22.2
Combat Arms units	2	22.2
Special Forces units	2	22.2
All military schools/units that have a physical component to it	2	22.2
Units participating in field training exercises	2	22.2
Air Assault	1	11.1
Special Forces Assessment School	1	11.1
Airborne	1	11.1
Anyone	1	11.1
Units in the southern United States	1	11.1
Units in the northern United States for cold temperature		
monitoring	1	11.1

Table 9. Civilian uses of the Mini Mitter Inc. VitalSense® Product.

Response	n	% of Total
Sports teams/athletic settings	6	66.7
Civilian emergency rooms	1	11.1
Firefighters	1	11.1
Police Officers	1	11.1
Drug Enforcement Agency	1	11.1
Construction workers	1	11.1
Bureau of Alcohol, Tobacco, and Firearms	1	11.1
Certain employers where monitoring the health of workers is		
critical	1	11.1
Elderly patients	1	11.1

Price of the system was a critical issue for RTB medics in that it would determine whether their military unit would be able to afford the CTM and thermometer pills, regardless of CTM's acceptability and functionality. RTB medics thought that the maximum price for an individual pill should be less than \$10.00. In addition, the CTM unit itself should be \$500 or less. These prices were based on comparisons with other medical monitoring products currently being used, and the alternative of using rectal thermometers with replaceable plastic protective caps that cost 19 cents per cap. A summary of suggested prices and maximum allowable prices for these products are listed in Tables 10 and 11.

Table 10. Suggested Price of the Mini Mitter Inc. VitalSense® Product.

Suggested Price Per Pill	n	% of Total
\$1.00	2	22.2
\$1.00 to \$10.00	2	22.2
Individual Suggested Price Per Core		
Temperature Monitoring Unit		
\$100	1	11.1
\$150	1	11.1
\$250	1	11.1
\$300	1	11.1

Table 11. Maximum Price of the Mini Mitter Inc. VitalSense® Product.

Maximum Price Per Pill	n	% of Total
\$1.00	1	11.1
\$5.00	1	11.1
\$Less than \$10.00	3	33.3
\$10.00-\$15.00	1	11.1
\$20.00	1	11.1
Maximum Price Per Core Temperature Monitoring Unit		
\$2000	1	11.1
\$500	1	11.1
\$250-500	3	33.3

Other products of interest to RTB medics are listed in Table 12. Two RTB medics mentioned that the use of ice blankets for cooling Soldiers are very effective, but are messy and potentially hazardous because of the leaking water and ice (e.g., someone could slip and fall from the puddles of water generated).

Table 12. Other Products of Interest to Ranger Training Brigade Medics.

Response	n	% of Total
Replacement technology for ice blankets would be less messy		
and less hazardous	2	22.2
Develop a general physiological stress assessment	1	11.1
Develop a method to neurologically stimulate the brain to heat up		
or cool down the body	1	11.1
Simple Global Positioning System (GPS)	1	11.1
Develop technology to heat someone up fast who is really cold	1	11.1
Develop a pill that can help a person retain water; stay hydrated	1	11.1

DISCUSSION

GENERAL VALUE

Thermometer pill technology has been used for some time in research settings, and has been used to a limited extent as a clinical tool (2). However, this is the first known use of the Mini Mitter Inc. CTM unit and pill as a clinical tool by military personnel. Feedback provided by RTB medics from both the formal questionnaire and small focus group discussions showed that this technology would be valuable for faster and more effective diagnosis and treatment of heat injuries in the field. Currently, core temperature in suspected heat casualties is assessed using a rectal thermometer. The major advantage of the thermometer pill over a rectal thermometer is that a patient does not have to have his clothing removed and a thermometer put into his rectum. Aside, from the discomfort and privacy issues the patient has to endure with the rectal thermometer, the thermometer pill allows core temperature to begin to be assessed in the field at the site of the potential heat injury, with continuous monitoring all the way to the ambulance or clinic. Typically, rectal temperature monitoring would only begin once the patient is in the ambulance. In addition, a Soldier who may be showing signs of disorientation but is still performing his training may be monitored by doing a quick assessment with the CTM without removing the Soldier from training. If the Soldier's core temperature was acceptable, he could continue with his training. If his temperature was too high and he was at risk of a heat injury, only then would he be pulled from training. Currently, a subjective evaluation has to be made by the RTB medic or Ranger instructor of a student who may have a heat injury. Only after this evaluation has been made, with the student pulled from training, is his core temperature assessed using a rectal thermometer. Even if he did not have an elevated temperature, he would be missing training during this evaluation for least a brief amount of time. Use of the thermometer pill technology would allow the RTB medic to more liberally assess an individual's health status without compromising the training time of those Soldiers not at risk. Hence, more measurements are likely to be made because false positive

subjective assessments do not cost training time. Likewise, there will be less false negative subjective assessments made by RTB medics because they should feel freer to assess core temperatures more frequently.

SPECIFIC COMMENTS ON CORE TEMPERATURE MONITORING (CTM) SYSTEM

Most RTB medics felt the CTM unit itself was acceptable in its present form. However, improvements were mentioned that could enhance the system and make it an even more useful diagnostic tool for the RTB medic. One recommendation was to improve the range of the device so that a Soldier's temperature could be assessed from farther away, perhaps up to 10 meters away, as opposed to the current 1 meter distance. Another recommendation was for the CTM to collect all of a Soldier's vital signs, not just core temperature. One RTB medic pointed out in the focus group session that often a Soldier's exterior signs or behavior coupled with working in the heat would lead the RTB medic to believe that their patient was experiencing a heat injury. However, these same signs could also mean a low glucose level. Having a tool that assessed all of a Soldier's vital signs would allow the RTB medic to differentiate these conditions and apply the correct treatment, (e.g., ice sheets for heat injury, sugar supplement for low glucose level).

Since much of Ranger training is done at night, another improvement to the CTM unit would be improved lighting of the buttons on the device, as well as an enhanced lighted display unit. Finally, a number of RTB medics described that future developments should allow data to be obtained from the CTM units and put on a computer network where senior RTB medics could review the data from a remote area and make recommendations on treatment. It was recommended that combining continuous temperature monitoring with a Global Positioning System (GPS) would allow for RTB medics to triage remotely and go to the location of a potential medical problem sooner, armed with better medical information on the nature of the problem. This would lead to better diagnoses and treatment of Soldiers spread out over wide training areas, such as was the case on the land navigation course during RTB training, or on the battlefield in actual combat. This recommendation coincides with the objectives of the Warfighter Physiological Status Monitoring Initial Capability (WPSM-IC) Science and Technology Objective (STO).

The greatest obstacle to the use of this technology is the cost. The Mini Mitter Inc. VitalSense™ pill system received Food and Drug Administration (FDA) 510k certification this year for use as an ingestible pill sensor. The devices now can be purchased off the shelf. However, use in military settings where many individuals are at risk, often for extended periods of time, would require many pills even to monitor only "at risk" individuals. Therefore, while the current cost of an individual pill is \$50.00 or more, the necessary cost for the pill should be around \$1.00 or so for this technology to be acceptable to the RTB. There may be other groups or individuals that require monitoring where the current cost would not be an issue. However, at the present time, groups such as the Rangers, other military schools, and military Basic Training would find the current cost of the Mini Mitter Inc. VitalSense™ system prohibitive for its use.

CONCLUSIONS

In summary, the CTM device would be acceptable for use by the RTB medic to improve medical diagnosis of heat injuries during Ranger training. At the current cost the device would not be adopted despite its obvious utility.

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APPENDIX A

MEDICS CORE TEMPERATURE MONITOR ACCEPTABILITY SURVEY

1.	Are yo	ou Range	er Tabbed?	No	,	Yes			
				1		2			
2.	Do yo	u have y	our Expert	Field Medi	cal Badge	e (EFMB)?	No	Yes	
							1	2	
3.	How r	nany yea	ers and mor	nths have y	you been	in the milita	ary?		
4.	How c	lo you as	ssess a Sol	dier's temp	oerature r	now?			
5.	How i	mportant	is knowing	ı a Soldier'	s core tei	mperature?			
Un	important 0	: Slight	tly Important 1	Modei	rately Import 2	ant Very Ir	nportant 3	Extremely Impor	tant
6.	How h	nelpful w	ould this sy	stem be in	assessir	ng the physi	ological	status of a S	oldier?
No	t Helpful 0	Sligh	tly Helpful 1	Mode	rately Helpfu 2	ıl Very H	lelpful 3	Extremely Helpf 4	ul
7.	Overa	ıll, how e	asy is the h	nand-held	monitor to	use?			
	remely ifficult	Very Difficult	Moderately Difficult	Somewhat Difficult	Neither Easy nor Difficult	Somewhat Easy	Moderately Easy	Very Easy	Extremely Easy
	1	2	3	4	5	6	7	8	9

8.	How	easy	to ι	ıse	were	the	menu	function	keys?
----	-----	------	------	-----	------	-----	------	----------	-------

Extremely Difficult	Very Difficult	Moderately Difficult	Somewhat Difficult	Neither Easy nor Difficult	Somewhat Easy	Moderately Easy	Very Easy	Extremely Easy
1	2	3	4	5	6	7	8	9

9. How acceptable is the display window?

Extremely Unacceptable	Very Unacceptable		Somewhat Unacceptable	Neither Acceptable nor Unacceptable		,	Very Acceptable	Extremely Acceptable
1	2	3	4	5	6	7	8	9

10. How acceptable is the size of the device?

Extremely Unacceptable	Very Unacceptable	Moderately Unacceptable	Somewhat Unacceptable	Neither Acceptable nor Unacceptable		Moderately Acceptable		Extremely Acceptable
1	2	3	4	5	6	7	8	9

11. How acceptable is the weight of the device?

Extremely	Very	Moderately	Somewhat	Neither		Moderately	Very	Extremely
Unacceptable	Unacceptable	Unacceptable	Unacceptable	Acceptable nor		Acceptable	Acceptable	Acceptable
1	2	3	4	Unacceptable 5	6	7	8	9

12. How accurate do you feel the readings were (i.e., did they correspond to other observable physiological or physical signs)?

Extremely Inaccurate	Very Inaccurate	Moderately Inaccurate	Somewhat Inaccurate	Neither Accurate nor Inaccurate	Somewhat Accurate	Moderately Accurate	Very Accurate	Extremely Accurate
1	2	3	4	5	6	7	8	9

13. If this system were accurate and available, do you feel it would improve your ability to evaluate a Soldier's condition compared to current diagnosing techniques?

No	Yes
1	2

			" Soldiers monitoring		alth status	s could be n	naintaine	d during		
N	О	Yes								
	1	2								
15. If ye	es to Ques	tion 14, w	hat are tho	se risk fad	ctors?					
16. If yes to Question 14, how would temperature monitoring improve the care these Soldiers receive (i.e., what would be done; e.g., would they be removed from training earlier if their temperature attained a certain level)?										
17. If you were provided this device, how likely would you use it in your job?										
Extremely Unlikely	Very Unlikely	Moderately Unlikely	Somewhat Unlikely	Neither Likely nor Unlikely	Somewhat Likely	Moderately Likely	Very Likely	Extremely Likely		
1	2	3	4	5	6	7	8	9		
18. About how many core temperature readings did you measure with the device during this evaluation?										
	w many ur during this			ture or no	n-reading	s did you ob	otain with	this		
	w quickly o do your jo	-	ed to obtain	n a core te	emperatur	e reading o	n a Warfi	ghter to		

21. Was the thermometer pill technology you used in this evaluation able to obtain a temperature reading within your preferred time frame?

No Yes

22. Overall, how acceptable is the device?

Extremely Unacceptable	Very Unacceptable	Moderately Unacceptable	Somewhat Unacceptable	Neither Acceptable nor Unacceptable	Somewhat Acceptable	Moderately Acceptable	Very Acceptable	Extremely Acceptable
1	2	3	4	5	6	7	8	9

APPENDIX B

TRANSCRIPTS OF FOCUS GROUP SESSIONS

Comments were not identified by individual volunteer. Focus group setup was set in a V shape, with volunteers sitting in Chairs 1 and 2 to the left of the moderator and volunteers sitting in Chairs 3, 4, and 5 sitting to the right of the moderator. The transcript below will refer to the volunteer's chair location only. This will allow anonymity of responses.

FOCUS GROUP SESSION 1

Moderator: Thanks a lot for participating in this. Basically, what is going to happen is I am going to ask a bunch of general questions. Try to talk towards the camera, or at least try to throw your voice that way. You don't have to look towards the camera, but if you talk like this **[moderator looks toward the back wall]**, the TV won't pick it up that well. Try to speak loudly, and don't interrupt one another. We will go until everyone feels like they said what they wanted to say. Sound good? OK?

[Everyone nods their head yes.]

Moderator: First question is, right now, currently, how do you guys currently treat heat injuries? If you suspect a heat injury, what is the general mode of treatment?

#5: First thing I do is pull him into the truck and get a set of vitals. That includes rectal temperature, uh core temperature, blood pressure, a glu **[means glucose]** stick, pulse, and respiration.

Moderator: Anyone want to add anything they do differently, elaborate?

#2: To add to what he says **[points to #5]**, we establish a level of consciousness, if he is coherent, because that is a big indicator of where he is at.

#1: And to add to that, the way I would get the rectal temperature is to strip him down totally, so that does add a certain amount of time to get a set of vitals.

Moderator: Is there any reluctance on the part of your volunteers, er students [referring to being stripped down]?

#1: They don't have a choice.

#3 and #4: Yeah, they don't have a choice [said in unison].

#3: Often they are unconscious, so they don't even know [referring to being stripped down].

Moderator: How do you get the clothes off? You see a potential heat casualty, you bring the guy into the ambulance, how do you get the clothes off? Especially if they are in backpacks, or suppose a guy falls? Say? What is the general procedure with multiple layers of clothing and things like that?

#4: Cut 'em.

Moderator: Cut the clothing off?

#4: Yep.

#5: Fastest way to do it. Sometimes if, say an instructor brings some guy, and he says this guy has been vomiting the whole time, I will say "Take his top off, take his boots off, and get the stuff off as fast as possible." That is usually the case with me.

Moderator: And when you are dealing with heat injuries, what is the biggest obstacle you face or have to deal with? We will start here **[points to #1]** and go around **[makes sweeping motion of pointing to all other volunteers]**. What is the toughest thing you have to deal with?

#1: Probably getting them to the truck, and if they are semi-coherent getting them to understand what you are going to do to them, so it is not a total shock [referring to the Ranger Student not being surprised with the medical procedures that will be administered by the medic]. Getting them to help you get their clothes off, so they stay somewhat aware of the situation. Getting them to tell us what they feel. Getting them to communicate with us so we can see if they can tell if they can see what their body is doing. Establishing communication.

#2: I think the biggest obstacle is identifying them. Of course, and getting them into the back of the truck and starting that initial treatment. Determining where these people are at. Where the Soldier is at. Getting their clothes off and getting that initial set of vital signs. There are various pieces that come into play. Communication with the other medic. Communication with the TOC [referring to tactical operations center]. Communication with the senior medic. There are a lot of pieces that come into play. Of course patient treatment comes first, but initially it is getting them in [referring to the truck], getting them stripped, and getting that set of initial vital signs. That is the first obstacle that we have to take care of.

[Moderator points to #3.]

#3: Getting them in [referring to the truck]. Getting the initial set of vitals. Getting a core temp. Usually they are semi-conscious, and they don't understand what you are saying.

Moderator: And the core temperature is rectal?

#3: Yes.

Moderator: I just want to make sure I understand what you are saying.

#3: That is pretty much my biggest obstacle.

#4: The hardest thing I find is actually going and getting the guy and getting them the 300 or so meters back to the truck. Once we have them there, if they are coherent, usually no problem. Guys can do stuff for themselves. But if they are not, they are usually squirming all over the place and I go and cut everything off. Stick in a rectal temp, and all that, and that takes a little bit of time.

#5: I agree with the points that have already been said.

Moderator: Which specific points that were already said do you agree with?

#5: Oh, I agree with that I want to stress getting that first set of vitals is what everyone is waiting on. You have your senior medic here [referring to Camp Darby Battalion Aid Station]. You have the TOC, the next room over. Everyone wants to know what this student's disposition is, where's he at? And this is how we base our treatment off of. This initial set of core vitals.

Moderator: OK, OK, great [nodding].

Moderator: In your guys' judgments, and we will go around starting with you this time **[points to #3]**, are there certain at-risk individuals? Where you say, oh, I better keep an eye on this type of guy?

#3: Oh yeah, most definitely. Usually at the beginning of RAP week, the guys that are usually sucking at the 5-mile run and whatnot. They are usually the ones that will be coming to the aid station first and usually when we send them back out, we then monitor them, and then they will be ending up on sick call. Yeah, that's the case.

Moderator: Great.

#4: Yeah.

Moderator: So you agree with that [referring to what #3 just said]?

#4: I do agree with that, and to go along with that, there will be guys that come here with prior hot weather injuries, and I would keep an eye out for those guys.

Moderator: OK. How would you know that **[referring to those with prior hot weather injuries]?** Do you look at their records?

#4: Yeah, we screen their records before-hand. Usually the higher-ups look at the records and pass the information down to us. Also, to go along with that, guys that

come in from other units that come from colder environments that don't have time to acclimate to this area usually are the ones that will be falling off [meaning the individuals that will have problems during the various Ranger training events].

#5: I agree with both of their statements. Usually when you have had a hot weather injury or cold weather injury your body is more susceptible to injuries. Your body is more likely to shut down at a lower temperature than last time because it has already happened once.

Moderator: I just want to clarify, when you say cold weather injury, do you mean cold weather injury for cold weather and hot weather injury for hot weather?

#5: Right.

Moderator: So you don't mean if a guy has a cold weather injury he is more susceptible to a hot weather injury?

#5: No, no, but what he was saying, where those who come from Ft. Drum **[upstate New York]** or Ft. Wainwright **[Alaska]** come down to this heat and humidity. They say it takes like 3 months for the body to fully adapt to the climate change. Something of that magnitude and what he was saying. And also, someone in the winter months who has gone down with a cold weather injury might be more susceptible.

Moderator: So in the cold, what are we talking about here? The same type of problems? Well, almost the reverse. If you have a cold weather injury prior to coming here and then you are out in the cold, might you be susceptible to that?

#5: Absolutely.

#2: I agree with these guys [referring to # 4 and #5]. Another thing, initially we screen the records. Let me backtrack. Prior to screening the records they [meaning the Ranger Students] fill out a sheet. They kind of tell us where they are at, their physical condition, if they have just recently been ill, if they are taking any medications. We look to see if there are any medications that would pre-dispose them to being a heat injury and we look at that too. To see if this guy is taking, for example, creatine or some sort of muscle enhancer, performance enhancer. That is a red flag that says this guy might be susceptible to a heat injury. So we look at that and, like they said [referring to # 4 and #5], if they are a prior heat injury, we look at all those things.

#1: I really agree with the acclimatization issue. Even from another unit, IOBC **[abbreviation for Infantry Officer Basic Course]** here at Ft. Benning. They may have been here **[referring to being at Ft. Benning, but not at Ranger Training]** 9 months, but they still go down. It all depends on your whole physical status. You get guys that, yeah, can pass the PT test, but it doesn't mean they are in great shape. They may have a few extra pounds, and most of these guys will go down, too. Especially because these runs, because the extra weight or the fat makes it harder on them breathing as

easy, or something like that, and that makes them go down easier, too [referring to guys that have extra weight or fat will go down especially on the runs].

#2: I just want to add to what he just said [referring to #1]. It is not necessarily the fatter guys. Even the more muscular, stockier individuals seem to be sucking on certain events.

Moderator: OK, thanks. Great. So, all of you guys, whether you used it [referring to the Core Temperature Monitor] or not, did you all at least see the VitalSense® monitor? Temperature pill monitor?

[All say yes.]

Moderator: What do you think, in general, of a device like that? Not necessarily that device, but a device that could measure core temperature without having to use a rectal thermometer.

#3: I think it is great. Anything that I could use where I don't need to go near a guy's rectum, I think that would be great.

Moderator: We'll just go right on down the line [motions to #s 4 and 5].

#4: I agree with that. Plus, you figure it should go a lot faster. Seems to be much quicker than having to shove a standard thermometer up his butt.

#5: I think it would work really well, especially as he was saying earlier [referring to #4], there are a lot of times that we have to go where a vehicle can't go and carry a guy out. It would cut down on a lot of time if we get them to the truck and say I already got his core temperature. I did use the device on the 5-mile run and on the students that fell out and were on the back of the truck. I found out who had the pill, put them together, and monitored them there on the back of the truck.

Moderator: General concept, what do you think **[looks at #1]**?

#1: I think it is a great idea. If we could monitor the whole class and get the pill to stay in a little bit longer where we could monitor everyone at once. I think the general idea is a great time-saver. It works, could, if you could just monitor guys when they come off of the Buddy Run or something like that and just get the temperature. And pull guys aside that may have a high temperature.

#2: I agree, especially when you have to go out to the field and pull a guy back to the truck. You can just get a core temperature right away, and when you get the guy to the truck you can start treating right away with the protocol for that particular temperature.

Moderator: So now we are going to move to, from the general idea of a product in this category to this product [referring to the Mini Mitter, Inc. Core Temperature Monitor unit]. Did you use this product at all?

#3: I had a chance to use the product once. I used it.

#4: I just played around with it the first day.

Moderator: But you did get to try it?

#4: Yes, yes I did.

#5: I used it on one of the runs.

Moderator: OK.

#1: I just used it at the initial briefing.

#2: Just at the initial briefing.

Moderator: We will get you guys first **[points to #s 1 and 2]**. From what you know of this product, does it seem to be an easy thing to use? Generally, about the VitalSense® product, what do you think?

#2: Absolutely easy to use. I saw one of the researchers using it after the foot march, and they scanned two students. Very quick, quick scan. They were able to differentiate who was who, and it was almost instantaneous when they got their temperatures, practically as they were walking by. Very easy to use, from my point of view.

#1: I thought it was simple to use. The main issue was getting them to take the pill every 2 days. Like if we were to get this on our own, and after you guys left and they were to implement it. That would be the biggest issue is getting the studs [studs refers to Ranger students] to take this pill every 2 days. Whether it would be us [medics] or the RIs [Ranger instructors] that do it [referring to who would be responsible for making sure the Ranger students took their pill].

Moderator: Speaking to this issue. Do you think it would be hard to get the students to take this pill?

#1: I don't think it would be hard. You would just have to make sure the RIs don't get too busy, where they forget or where the studs forget. Unless you sit there and watch them [referring to Ranger students] and tell them to take it, it goes in their pocket and a few days later, whoops, I forgot to take it. So you have to actually watch them to make sure the actually take it.

Moderator: And is that a possibility?

#1: Yeah.

Moderator: And maybe for the at-risk students?

#1: Yeah, if you had a select group of students where you made sure they took it, it would be easier, we could give it with the ORS packets [salt packets given by the medics to help Ranger students retain more water and reduce likelihood of dehydration].

Moderator: OK, OK, good [turning to #2]. I started with you [motions we started with #1], and I liked your idea [#2], so I want to make sure you address that, too.

#2: What you said made sense. At-risk students getting the pill. Not necessarily every one getting the pill. It would be ideal if everyone getting the pill, in an ideal world. But I believe it would work just fine if we identified those at-risk, it would be a good thing.

Moderator: Any comment [turning to #3]?

#3: I think it's a great idea, anything that cuts down on the time where you can get to the treatment faster is a great thing.

Moderator: And to address the idea they were talking about **[#s 1 and 2]**. What do you think about students taking the pill? Would they do it reliably and without resistance?

#3: Yeah, I think for the most part they would. Especially if you explain the process to them and you explain the alternative, the rectal temperature, which I don't think most would want.

Moderator: Good point. [points to #4] What do you think?

#4: I agree with that wholeheartedly. I think it would be actually, I think it would be pretty easy. Point out a certain time of day where you would say we all get checks and they would come out and have everyone just stand by and do a 5-minute check to make sure the pills are working. And if it is in there, great. And if not, pop another one in. I can see that happening. Some times it could be more effective with people having prior histories, people slotted out with them being checked out.

Moderator: [pointing to #5] You're probably the one that used it the most, so a little incite into.

#5: [interrupts before Moderator finishes] I thought it worked really well. Since, to refresh what they were talking about [points to #s 1, 2, 3, and 4], it would be a good idea especially for at-risk students or anyone who has been a heat casualty here and

we return them to duty, whether it be the same cycle or the next cycle. Well, now you have to take this **[referring to the pill]**, and now we are going to monitor you. It's a good idea, like he said, I think it is possible **[nods to #4]** to allot a 30-minute time period to check the pill. If it is gone, say "Here is a new one." I liked it. I think some areas it worked really well, and I think there are some areas it can be improved on. But I know, for the most part, that if it only worked the way it did, it worked just fine.

Moderator: Which leads me to my next question. It's like you read my, its like you had my list **[moderator shows his list of questions to the volunteers]**. What are the most attractive features and what are the least attractive features of the product?

#5: My favorite thing was its size. It was small, it was easy to use, you guys [referring to the USARIEM research staff] gave me that little pouch which I clipped right here [shows his belt on his right hip] on my belt. It was user-friendly. It's just that the actual screen of the device, everything was perfect on it. Some of the things I didn't like were in actually reading temperatures. I noticed the delay. When you say a 15-second or 30-second delay, it doesn't seem that long, but it is. When those guys jump on the truck, or we put them on the truck because they are unconscious, I could have gotten a rectal temperature a lot faster than waiting for that device. I think if it was sped up a little bit, or you could just emit something where you could just activate one, if you have 3 or 4 of them right there instead of waiting for them to go through their cycles you could just zap them [points with his hand at moderator as though monitoring him with the device, then closes his thumb on his hand in a push-button motion] and send a signal or whatever and read their temperature immediately.

Moderator: I just want to clarify something. So if you point [moderator imitates the same motion as #5 did], one of the Soldiers mentioned to me in passing, that if you point the thing at the guy you would get temperature feedback right away. Is that what you are talking about?

#5: No, that is actually another thing I noticed. I had to get quite close to them. I don't think the one meter [referring to the distance radius the device is supposed to be able to detect] was working. I actually had to turn the sensor towards them and get this close to them [with his hand he demonstrates that he had to hold the device about 3-4 inches away by holding his hand that far away from #4's chest]. I was timing it on my watch thinking I wasn't holding it long enough. So I would hold it, and I would get closer and closer, and finally I would get a reading. But, yeah, maybe if the signal could work both ways where if you could activate it to read a temperature and it could get it back to me, maybe it would be quicker, maybe it wouldn't. But for the way we used it, I think it worked really well. Especially in the application if you were to bring someone out of the field, out of the woods, or as they were walking up. Or with the instructors if they had it, they could use it, so if a guy went down with these signs, a guy is vomiting while in route, get his temperature and these vitals and call them into us. And we pull up and, say, they have a temperature of 103°, we put him, put him on the truck, strip him down, ice him down, and we would know exactly what to do right away.

Moderator: So all you guys, **[referring to the rest of the group]** just think when you would like improvements of the least attractive features, think anything is possible. Not anything will be possible, but from this little focus group think anything is possible. OK? What would you like to see **[pointing to #4]**? What do you think are the most attractive features and the least attractive features?

#4: Let's start with something that needs improving. I know that the battery life isn't all that great when it is in medic mode. Especially while you are running a couple of hours on a lithium battery, it is sucking up a lot of power. Overall, I liked it, but like as he was saying a second ago [points to #5], if you could do an instant activation with the transmitter right then and there to get it. Because by the time you get the guy in the truck, take his core temperature—I personally think this thing would work better because you don't have to take off all his clothes and get him prepped and all that other stuff before you can get a core temperature. And even those digital thermometers take a little bit [meaning a little bit of time] to actually read. So, I would think that this would be a lot faster, but I think at the same time that instead of having to wait, you should be able to point and check and then get your temperature.

#3: I like the compact size of it. It doesn't get in the way of anything else, like if you have your aid bag. You just strap it on your belt. Of course what he was saying earlier [points to #5], if you could increase the range a little bit. You have to get really close to get an accurate reading. Other than that, it is pretty good.

#2: I agree with the distance factor portion.

Moderator: As an improvement?

#2: As an improvement. I really didn't use it, but as you said, if anything is possible, if it could get a complete set of vitals through this type of device.

Moderator: Such as, such as, heart rate?

#2: Heart rate, maybe, I don't know if you can get any kind of pressure, from arterial pressure from the pill going through your digestive tract, but that would be interesting. Maybe.

Moderator: I just want to focus on that? What are the vitals that you would like to have?

#2: Well of course you have your basic vitals; respiration, your pulse rate, your temperature, and your blood pressure. Those are your basic four. Another thing that would be interesting is if it could send a signal somewhere else with the vitals. Because we are out in the field, and you know it could be connected to another relay where the Doc or someone back at the station can say this is who the guy is and these are his stats immediately. That would be interesting to see.

#1: Kind of what he touched on [pointing to #2]. If it had a longer range where when they are walking by you, you could stand 10-20 feet away from them and still get their temperature. You wouldn't have to go to each person individually. And being out in the field it would be nice if you had a stronger signal and transmitter. You could have a computer back here [Camp Darby Battalion Aid Station] where it would have every Soldier's temperature automatically come back here. The senior medic could then look at it. And you wouldn't have to call it in on the radio per se. He could then say alright bring him in, or yeah treat him out there and he can go back to training. So you could have one big database and then have a lot of little databases out there [in the field].

#2: That is very interesting because with what he was saying, made me think of something additional. Lets just say, in a perfect world everyone takes a pill. We could actually have a station back here where we are monitoring every stud that is out there. And when a certain temperature is reached in a certain stud, an alarm could go off and you could contact a certain medic and say Roster #356, his temperature is getting up there, let's go check him out. That, that would be awesome.

#5: That is exactly what I was going to say. If you could incorporate some kind of template into the hand-held or start with the hand-held as a walking thing into an event and have a little asterisk or something go up. And you could say, you come with me, and you come with me. And like he said [pointing to #2], in a perfect world we could monitor it here and have something go off and say OK, this guy has reached 101° or his blood pressure is climbing or his heart rate is really high, or you know one of the vital signs that isn't a baseline for what we do for heat injuries is glucose levels. If any of those reach a certain level, where I guess you would say flag him, we could then go and check him out. Or at the end of an event we could say, hey these people need to come with me to get checked out.

Moderator: Here is a question that I always had, and I was wondering what you guys thought. Well, you know **[points to #5]** because you definitely used it. You saw on the screen a pill number come up instead of a subject number. Was that easy to deal with or was that complicated.

#5: It was easy in the application that I used it because I didn't have to call anything in. I just said, hey pull your dog tags out, and let them hang **[subject numbers were on back of the dog tags]**. Now if you could have something where the pill number correlated with their roster number, that would be so much easier because we don't use names over the net or over the radio here. You are Ranger or roster number whatever. So, I could just say what is your roster number or I could just look at his roster number, 1-2-3. 1-2-3, there it is and that would almost, that's their name when they're here. I didn't see a problem, but if I did have a guy go down, and let's say I was monitoring more than one and wait, one, that's his roster number, but that's his pill number, it is this. And that's his temperature and now I got to call in an extension with his roster number, and I could see sometimes getting mixed up with the numbers.

Moderator: What about you guys? Do you want to weigh in the roster number vs. pill number [issue]. Do you all agree?

#1: It would be a lot easier to keep track of it [referring to pill number corresponding to roster number], because you wouldn't have to get out their dog tags, because that is their name in Ranger school [referring to the number that comes up on the CTM unit].

#2: [Nods head in agreement.]

#1: That's what we go by here. What they are signed in by, roster number. Whatever, whatever. They know that and they step up and we get their temperature.

#4: Some guys who drop down, possibly unconscious, and/or who are not all there, we ask all the time their roster number and all that, and they can't tell us, then they are going to need treatment.

Moderator: Do you agree? [Looks at #s 2 and 3, referring to use of roster numbers instead of pill numbers.]

#3: I agree.

#2: lagree.

Moderator: Now we are going into, OK, we are getting close to the end of it. Let's say we get you the system you guys like, with some of the improvements you mentioned. How much do you think, and I don't know if you actually know this information, but how much do you think it should cost for the actual pill and the actual monitoring unit? And, think about it working within the budget that the Rangers have. And, if you don't know, let me know that, too.

#5: It, I think the price would depend whether I am on the selling side or the buying side.

Moderator: You are on the buying side. Let's say the price could be between \$10,000 and \$100. You have to make a decision, somewhere in that range. What do you think is a reasonable price that you guys could afford?

#5: I think in terms of the actual pills, I think you are going to have to look in the dollars per pill. Let's say we have 200 students for a round number, and one pill times 2 days. You will know some of the students by name because they go through here because they recycle and recycle. Let's say in terms of the monitor, you give one to each medic, and one per each instructor. And you got to account for wear and tear, and we're going to break them. I'll tell you right now we're going to break them, so I'd say it would have to be as low as possible, almost calling off the profit on them for us to use them because of the numbers that we would have to use.

#4: Inexpensive, is the best.

Moderator: What is inexpensive?

#4: Dollar range for the pills. General range is dollar range.

Moderator: Dollar range, do you mean less than \$10.

#5: Exactly, that is what I meant.

#4: Yes, somewhere around there with \$10-\$20 max. I know what's involved with it. But, if we could get if for around a dollar a piece that would be great.

Moderator: What about the unit itself?

#4: I could see the unit itself going for around \$300. With the whole ideal system [referring to the transmitting system, too] going for a couple of thousand dollars.

Moderator: OK.

#3: Yeah, I would say for the pill, about a dollar amount to go up to \$10 or \$15 dollars.

Moderator: Max?

#3: Yeah. Because there is a large number of students that come through here and whatnot. And for the monitors I would guess about \$150 a piece or something like that.

Moderator: You guys [looks towards #s 1 and 2]? Think about the medical equipment that you use.

#1: I really don't know the price of anything because that is not what I deal with. But you definitely have to consider mass production for the pills because we would be going through these things quite a bit.

Moderator: OK.

#1: So maybe the more you produce the cheaper they would get. And I also kind of think of this like a cell phone type thing where you have your main home base and you put up a tower out at Darby [meaning out in the field at Camp Darby], or something like that, so you can get a signal back here [Darby Battalion Aid Station]. And then each unit would be considered like a cell phone. You have your home base, your tower out there, and you have all these cell phones that feed into the tower to come back here [meaning the home base at the Darby Battalion Aid Station]. So whether it be a flat cost per unit that would be cheap and maybe a monthly thing on top of that to operate the signal. I don't really know the price.

Moderator: OK.

#2: I would say, I would say no more than a dollar a pill. And I would say no more than 250 for the unit itself.

Moderator: 250 dollars?

#2: Yes.

Moderator: OK and now, we already touched on this with the heart rate and things and to an extent, you know of sending a signal back to a home base. But are there any other features that we haven't talked about that could be extensions of the product? By extensions, I mean, you know, to make this a better product, to make this product a slightly different product, so that it measures more than just measuring a temperature pill and vital signs?

#5: One thing I'm not sure who it was from your group, there was something that I was talking about that could measure water intake. If we could also measure what his **[meaning a Ranger student]** fluid intake is. And his cooling is. That way we could say he has got his 8 quarts or he has his 1 quart an hour. That way we could say maybe he is just running a little hot and let's just watch him. And like he said **[referring to #2]** earlier, if we could get a full set of vitals at a touch of a button, that would make things a lot, a lot easier on our end.

#1: I think one of the key vitals, not the key vital per se, but that would help us a lot would be the glucose. Because, if you can get the glucose, you can tell if it is a heat cat [cat means casualty] or whether they don't have enough sugar in there. Because, [pause] which would be two totally different kinds of treatment.

Moderator: But some of the symptoms are the same?

#1: Yeah, cause they're not all there. And we are going to be thinking heat cat because it is really hot outside, but maybe they haven't been eating as well as they should be. So we're going to be icing them up, when we should be giving them glucose to bring up their blood sugar. So you got two different kinds of treatment.

Moderator: Do you guys see if there is any value of instead of putting it **[meaning the thermometer pill software]** on a CTM unit of putting it on a PDA unit that you might already be carrying? Or is that not a big issue?

#5: I don't really think that is a big issue.

Moderator: It would be OK?

#4: It would be OK.

#1: We don't really carry any other equipment that would go with this.

Moderator: And you thought that the screen was big enough? Was fine?

#5: One thing about the screen was that, it's a very minor thing, but should be an easy fix, is that when the road march started, I mean I'm sorry, the 5-mile run started, when the first guys started it was still dark out, and.

#3: Damn [laughs].

#5: And, I'm looking for the light button, and I'm pushing it [demonstrates by repetitive pushing on his hand], and nothing is happening. And I finally find it and I push it and I bring it over here [moves towards moderator] and as soon as, the damn light would turn off. Maybe if you push the button and the light stays on a little bit longer, or if the buttons are continuously lit then you could see. OK. Then it has been the allotted time. I hit the button, I got the light, and I do what I got to do, record the core temperature. But the lighting system [#5 Stops talking].

Moderator: Needs to be [#5 inferred the last word to be improved, which it was going to be].

#5: Exactly, especially around here.

Moderator: Where?

#3: They are in the dark.

Moderator: Some of the activities are in the dark?

#5: When you have squads that don't come in until 3 or 4 in the morning sometimes, so from dusk until then you have to bring the flashlight out. You'll do what you have to do, but the light is pretty **[stops talking]**.

#4: Any light is something.

#5: Right.

#1: Maybe have a sensor when the light level reaches a certain level it automatically kicks on. Where you don't have to do anything. You just have it sitting in the truck and you don't have to push any buttons. It just lights up.

Moderator: Nice. What other military groups besides the RTB could use this?

#3: Anyone.

#3 and #4: Basic Training.

#1, #2, and #5: Basic Training [everyone nods].

#4: We've heard a lot more stuff recently that Basic Training has had a lot more action than we have had recently.

Moderator: So all you guys agree. Basic Training [all heads nod yes].

#1: Pretty much any school. Basic Training, Airborne.

#3: Air Assault, Ranger.

#4: Air Assault.

#5: Pretty much the physical schools. Like he said, Ranger, Air Assault. You could take it anywhere where there is a lot of physical training. I think Basic Training would be the next spot to hit because I heard stories of guys dying. I would say when people come here, 95% of them know the shape they need to be in when they come here. But when you go to Basic Training, you got guys coming in off of the street. And they expect them to do pushups, and run in this kind of weather [meaning hot weather].

#4: They also aren't lucky enough to have the kind of support system that we have out here with all the medics covering everything. They don't have that at all.

#5: Right, right.

#1: It also depends on location. There are a lot more units in Georgia, South Carolina, Louisiana, Texas. Places where the heat and humidity are high. You wouldn't necessarily need it as much in Washington **[meaning Washington state]**, or at 2nd Battalion, or like that or Alaska or units in any of the northern units where it stays somewhat reasonable out. As long as you drink enough water you should be able to keep your temperature down. Like here, you can chug water all day and you are still overheating.

Moderator: Unless you are worrying about the other end [meaning Soldiers getting too cold].

#1: Yeah, with the cold injuries it would be great up there, but then not back here.

Moderator: That leads me to the next question. Any group that would not need it? Or could everyone use it in certain occasions?

#5: I think one thing that kind of ties into what he touched on **[meaning #4]** is if a guy goes down at our school here or has a problem, we can give him an IV, or drop a line in him. We can cool him down and send him on his way. Where if you were in Airborne School or in Basic Training, they're not going to stick a line into him, they are not allowed to. If they go down, they are going to the hospital. So I think that it is good

here, but it would be even better where they don't have the support personnel passing out Gatorade, passing out dehydration salts. You know, dropping lines in guys that are over-heated. Like he said **[points to #1]**, with the northern units, it is not really a necessity.

Moderator: Everyone agree?

#1: You could also have it where as everyone here, each medic at like Airborne or Basic, maybe has their own unit [meaning the CTM unit]. Or a bigger supply than other units [now units mean Airborne or Basic compared to other military specialty units], where they only pull them out on certain occasions, if they had a big exercise or something like that. They wouldn't need it all the time. So they wouldn't need 3 dozen units [meaning CTM units] and a mother unit. They could have 3 or 4 individual units and take the pill when they need to, but not all the time.

Moderator: I know you guys are all in the military. Any civilian uses for this technology?

#1: Construction. It was a big problem back home with people overheating and stuff like that. When you are building a house and you don't have a roof over your head. Gets pretty hot. Some of the guys down on the main post, building new barracks, they are in jeans and boots because of the work environment. It gets pretty hot. It is similar to being a Soldier.

#5: I'm from Florida and I've dealt with the heat, but high school football practice. Anything, like that.

#3 and #4: [They laugh and nod in agreement.]

#5: Any time you are going to be out in the sun whether you are playing a sport or a job or anything where you are going to be outside in the sun doing strenuous things, lifting boards, running. The civilian application would be pretty much like that.

#1: High school sports.

#4: To keep in civilian ERs. Every once in a while you get someone coming in, not as often as right here **[Ranger School]**, but there are certain towns in the summertime that are so hot and hazy. People start falling out. I've heard people start dying, especially older folks. Just in some locations, you're like hey, get him to the hospital to monitor them.

Moderator: Do you two guys agree with this **[looks at #1 and #2]**?

#2: Yeah, yeah, I agree. I think a civilian application, I don't know what the liability is for a civilian employer for their workers, but I think if there is a liability there, which there always is, with people getting hurt on the job. That would be ideal, with recognizing

someone that could be going down right away. Make it part of the application of when you go get the job in the summertime, everyone takes a pill.

#5: I thought of something that came by. If you were able to implement this with civilian EMS where you could give it to someone that they needed to take constant vitals such as the elderly. You could have them swallow a pill. A lot of paramedics get calls for chest pains. That could be numerous things. You give them this pill and then the whole time you can monitor their vitals second by second. Then when you get them to the hospital you can say we given this guy the pill and they can then monitor them in a hospital setting. You can hook someone up to an EKG. You can monitor them. That could be a possibility too.

Moderator: Is there any other technologies or information that a medical facility like where we come from **[meaning USARIEM]** could help you guys out with? Anything? Aside, kind of moving off this last question, for example, we used some GPS units out there to track people, as an example. Is there anything else that you can think of that we as an Institute could help you out with. Either information-wise or trying to get products into your hands. What could we do to try and make your guys' jobs easier **[pause and looking at blank faces]**? Or maybe there isn't anything, and that is OK too. You're doing fine, and no help is needed.

#1: Maybe if you could implement something as detailed as this, that is more general, that could rate their overall body stress, where it wasn't doing temperature per se, but it would just kind of looked at the physical condition, the condition of everything. It would just rate everything on a scale of 1 to 10. That when something reaches a certain level it would let us know, that in general, something is wrong.

Moderator: What do you think? Anything [points to #2]?

#2: Nothing.

#3: Nothing.

#4: Come up with something that could help cool down a person faster, but with the same effectiveness as just throwing on an ice sheet over a person.

Moderator: So if there is another way? Another technology?

#4: Another cooling method without getting ice and water all over the place, which creates a little bit of a hazard.

#5: I agree, that is something we can use. And it could go both ways. Where it is 40° below up in Alaska, in the cold, something that could heat them up a lot faster then taking his boots off and sticking his feet on top of the guy next to him.

Moderator: OK.

#5: Other than that, I can't think of anything.

#1: Something along with that, where you have something that could send some kind of impulse into the brain. I don't know how detailed you guys are looking to get here, but maybe you could send an impulse into the brain that sends a signal to your internal heater or something like that. It would be all internal and affect the neurological system.

Moderator: OK. Now I am just going to summarize briefly what we all talked about and you all say if you agree. In general, you liked the idea of this concept. You like this product in general. A few improvements; the lighting system could be a little better to use it in the dark. It could use a little stronger signal so that you don't need to be right on top of the guy. You feel the price of the pill should be somewhere in the dollar range. You feel that the price of an individual unit should be in the range of \$150 to a max of a thousand or so. As an extension of the product you would like to see if it could get a few other vital signs on the product. And by the way, we are working on that. The problem is that you need other sensors like a blood pressure cuff or something like that. The VitalSense® unit will do that though. Other groups, Basic Trainees might be able to use this product. People in sports settings or construction work might be able to use this. And, basically that is it. Does everyone agree with that? [All acknowledge yes.] Hey, thanks a lot. This was great for us and I really appreciate this. Thanks a lot. Thank you.

FOCUS GROUP SESSION 2

Moderator: Basically, what we're going to do is I am going to ask you a series of questions. We are going to go from more general questions to more specific questions. I am not going to use anyone's names, so I will just point or kind of look at you [moderator demonstrates by looking at #2 who acknowledges that he understands]. Everyone should try and contribute. So we will just kind of go alternating around [moderator demonstrates with hand gesture that every one should participate]. Everyone should give their ideas. We will take as much time as we need to complete every question. There is no right or wrong answers. So, any idea that you have is good. Try to speak, you don't have to look at the camera, but try and not talk back here [moderator turns his head and looks toward the back wall]. Try to talk out into this general area [moderator points with his hand the space between the volunteers and the camera]. Any questions?

[All shake their heads no.]

Moderator: All right, so we are going to begin. Do you guys currently have any problems assessing temperature [means body temperature] here at Ranger Training? I will start with you [points to #2].

#2: Uh, no. Protocols we have here when we have a heat injury are to take a rectal temperature. That is one of the main priorities that we have here.

Moderator: And can you just explain how you do it? What happens? A guy goes down, what happens?

#2: When a guy goes down, we get them to the Rodgers Aid Station [referring to Camp Rodgers Aid Station, one of the medic aid stations for Ranger training at Ft. Benning], and we use ice sheets. They are sheets that are dipped in ice that cools the body temperature. But prior to that, we take a rectal thermometer and get that initial, initial rectal temperature. That way, we know the severity of the patient [means severity of the injury of the patient]. If it [means rectal temperature] is over 102°, we know that [means that we know we might have a heat injury].

Moderator: Anything to add [looks at #3].

#3: No, no, not really. Everything he said is true. Obviously, we have to strip all the clothing off.

Moderator: And how does that happen?

#3: Well, we have these high-speed scissors [everyone laughs]. The Soldier gets evaluated first by the medic on the ground. And then we put them on the bus [referring to one of the transportation vehicles, like the trucks and ambulances that transport injured Ranger students to the aid station], obviously we are accounting

for privacy when we strip them down. It is core temp, vitals, get taken, and that is the most important thing. Then the ice sheet. They're ice-sheeted. Obviously, the senior medic makes the call if they are coming back here [referring to the Darby Aid Station where the interview is being conducted]. We're just going to hold what we have there [referring to holding a patient] and continue treatment.

Moderator: Do you agree with all, everything that they said?

#4: I agree with everything they say. And just to add, we have two trauma bays. And then with each of the two trauma bays we have an automatic ice sheet that we can lower and raise the temps on. So the ice sheets that we throw on top, they'll heat up pretty fast according to his body temperature [means that they can cool off fast, but also can heat up again if they bring the body temperature down too much].

Moderator: OK, OK [moderator acknowledging he understands; #2 and 3 nodding their heads in agreement with what #4 is saying].

#4: But, we can lower the body on top of the table, we can lower the body almost 45°. We can really do what we have to do.

Moderator: It comes down fast [referring to core temperature]. Now, what if they have MOPP gear or some other type of personal protective equipment on? I don't know if they even do it here, but if they did, would your process still be the same. You would cut it off [referring to any additional clothing]?

#2: We would strip it off of them. Yeah.

#3: Yes.

Moderator: OK, so right now, and we will start with you **[points to #4]**, how do you currently assess it, is it rectal? Is there any other way you can measure temperature?

#4: Core temp?

Moderator: Yeah.

#4: Just rectal.

Moderator: Everyone agree?

[Everyone nods their head yes.]

Moderator: Everyone agrees. So, not thinking about the actual product, but the general idea of measuring core temperature with a remote sensor, such as with a pill, what do you think of that? What do you think of the general concept, not of this product, but of the general concept in and of itself?

#2: I think the concept is pretty good because to actually initiate a rectal temperature is not something that everyone is comfortable with. If you catch a stud when he is running, you can say "slow down," you know what I mean, "let me evaluate you," you know, early intervention is the best thing.

Moderator: [looking to #3] Agree? You totally agree?

#3: Yes, totally agree.

#4: I think it is a great concept, too, not only because in this unit, because, or in this school, because we do a lot of males, but what about the units that have a lot of females. That is going to be a big plus up, because we have problems sometimes with a thermometer up a [referring to a patient's rectum], with a guy, sometimes they have a problem with it. So females are definitely going to have a [means have a problem with having a rectal temperature taken especially by a male medic]. I think it is a great concept.

#3: I think it is going to be good. Just imagine you are on a mission where you have full kits on, you got MOPP on, full gear. Let's say you're in Iraq or in the middle of the desert somewhere, that is automatically adding 10° to 20° on. And if you had a device that continuously monitored somebody, I mean you would identify that person before he went down.

[#s 2 and 3 nod heads in agreement.]

Moderator: A time saver.

#3: Yeah.

Moderator: Speaking to the product that was used in this study, the VitalSense® pill. What did you think of this product? Well first of all, did you all get to at least try it?

#2 and #3: Yes.

#2: Well, I didn't swallow it.

Moderator: No, no, I mean did you get to try the monitor [#3 and #4 laughing].

#2: Oh, oh yeah.

Moderator: [turning to #4] Did you get to try the monitor?

#4: Yes, yes I did.

Moderator: So everyone got to try the monitor. So thinking of this product, what did you think of this product in general?

#4: I think the product was really good. I mean if the pill could just stay in the system a little longer.

#2: That's what I was going to say.

#4: If there was a way some how to slow it down.

Moderator: To slow down the passage through [means through the GI system].

#4: To slow it down, or anything. Time-wise, it was good and everything like that, maybe on a situation like where we are here at the school, maybe you can get a bigger device, maybe a hand-held device [points with his hand toward an imaginary patient], like a radar gun or something. We don't need the little ones [referring to the CTM devices used on this study], because we have our vehicles. So, you could just aim, and we don't have to because if we could just aim it at them during training and get [means get a temperature], that would be a major plus.

Moderator: So your thing is that where the technology should go is not necessarily the size being an issue, but it's the functionality of getting a temperature on someone who is farther away?

#4: Yes, farther away, or in our case [#3 interrupts].

#3: Without interfering with the training itself [#4 interrupts].

#4: Right, if we could mount it to a vehicle, like if they are in front of us, like for the road march or the 5-mile run, we can just sit there and monitor them.

#2: And when the students are ready to go down, they often don't know it.

Moderator: And you were going to say [pointing to #3].

#3: Well, and these devices are great, but with GPS technology, maybe we can backfeed into a database so that a medic from the aid station could monitor this guy continuously. So you could have a main computer that does that all for you.

Moderator: You mean remotely?

#3: Exactly. So if you're saying you have medics on the ground, say you have a patient in Squad, Platoon 1, Squad A, and its roster number such and such. His vitals and core temperature is this. You can check him out. And you can automatically send your medics, who are already there on the ground covering that event to go right to them. And that goes for real world missions later on with the big Army, too. And they

can identify what building this guy is in and what area his specific mission is happening, this guy's vitals are, and what's going on with this guy, so the medic can go check on him. If we can account for the communications technology, we can get the medic exactly right there, so maybe, I mean that [#3 stops talking without finishing sentence].

#2: Like he was saying, it is an excellent tool if it [referring to the pill] could stay in your system longer. I mean, I know this is the first initial test that you guys are doing, and it is excellent, but as the technology evolves, you know, they have the skin patch. I don't know how accurate that would be while you are in the field. But if it could stay in your system longer, that way it would be less, it would be, you know, less man time for the person. That way you take it, you eat it, you swallow it, and a couple of hours later they lose it.

Moderator: Since you bring up the skin patch, I just want to introduce something. We do have other technologies, like the skin patch, which you have to apply, like respiration devices, things like that, that can be used with this system. One of the issues is, with the pill, you just take it. Do you think there would be enough time **[meaning enough time to apply a skin patch or other device]**. Would there be resistance to it? Or do you have enough control, where you can say hey, I think we need to use this technology?

#2: Anything medical that can help stop a student from going down would be good.

Moderator: [pointing to #3] Do you agree?

#3: I think that if you explain it to the individual, it is obviously a selling point. If you can explain to the student that you are trying to keep them in training, they will be more accepting of the issue. Like if you are feeling ill [referring to a Ranger student], you've had a temperature of whatever, you've been feeling sick, we're going to give you this medication that is constantly going to dehydrate you. Or we can give you this pill, and we can constantly monitor this guy. And if he is running an event and obviously his vitals are elevated, we can monitor him. Obviously, we can keep an eye on him. That's important. Anything that keeps these guys in training, instead of later down the road, going down for something that you could have prevented. If you can head things off before it even starts, well [shrugs his shoulders and stops talking].

Moderator: You agree?

#4: Considering overall, I think between the two [meaning the pill and the patch], the pill would work better than the patch in this environment. Considering some big area or some place else, maybe the patch would work better, but I don't think it would stay on in this place with half of the stuff here [means things Ranger students have to do during the course].

Moderator: You agree [looking at #s 2 and 3]?

[Both nod yes.]

Moderator: What do you think are the most attractive features? What are the things that you like best about this product and what are the things--I know we've already touched on this, but I just want to make sure we cover it--what are the things that can be improved upon. If you can think of one thing that you liked, at least one positive thing, and one negative thing, that is one thing that could be improved upon.

#2: For the positive thing, once they swallow the pill, the need for a rectal temperature is eliminated. I think that is one thing that the students themselves would agree upon.

#4: I agree with that.

Moderator: You agree with that [looking at #3]?

#3: Yeah.

Moderator: Going back one question, who are the at-risk Soldiers that come through here? And if there are **[meaning at risk students]**, who are they.

#2: Normally, we wouldn't take anyone who has had a prior heat injury for a summer class, but if they do slide through, and anyone who might be taking a supplement. They say you're not supposed to take supplements prior to coming to Ranger School, but sometimes they slip through the cracks, and if we could monitor them, that could help them from going down.

#3: Soldiers that come from cold weather climates, cold weather areas, Alaska. The Army, they're deploying, a lot of the students that are coming here may have had only a month or two to train up from coming back from a deployment. That is, to train up before they come back here to go to school. They may not be in the best shapes. They may have been in the best shape of their life when they wanted to come here to Ranger School, but they've been getting back from their deployment and maybe not have been able to exercise the way they have wanted to, to come to Ranger School for the past year, so those guys are at risk. The majority of guys we see here are guys like that, or people that haven't been training necessarily to come here. So you get students, officer, officer guys from the infantry school here [referring to Ft. Benning Officer School], you get coming through here who haven't necessarily been acclimatized to this type of training here.

Moderator: OK, OK. Are there certain at-risk events that you are aware of, not only at RAP week, but throughout all of RTB Ranger training? And if there are, what are they?

#2: 5-Mile Run, Buddy Run

#3: [turning to #2 to correct him] Other than RAP week.

#2: Oh, oh.

Moderator: And, and you can include [# 4 interrupts].

#4: All of Ranger school is an at-risk event. You are being put through challenges mentally, physically, and not only are those two parts of your body, your organs and everything have to comprehend what is going on. You are going through different environmental changes; you're going from here **[Phase 1 at Ft. Benning]** to mountains to swamp. You are just going around and everything is different, and it impacts on your entire system.

#3: Initially, food deprivation and sleep deprivation are not a huge issue in this phase. However when you get to the mountains and Florida [meaning the swamp phase], that's when it really starts. I mean, you start feeling the no sleep, the no food, it starts, when you start burning more energy than you are taking in calories. And that's where it starts kicking in, and the patrols start getting longer, and the walks, and in the mountains obviously, you got to climb the mountains [referring to Phase 2, mountain phase of Ranger training]. The weight is about the same; you still have the same load. And in Florida you still have the same load, usually more, because you now have boat operations that you are planning for. So you have that equipment that you have to carry. So, the whole thing, like he said [points to #4] starts tracking. And especially the next two phases, that's when you really start to feel tired, and you really start to feel hungry. And all of the, and all of the little lickys and chewys that you are, you start to begin missing, That's what you start to miss, and it really starts to hit home; that hey, I'm in Ranger School and this stuff is hard.

Moderator: [looking at #2] Do you agree with all that they have said [meaning what #'s 3 and 4 said]?

#2: And also the inability to heal. They don't have time to, if they sprain an ankle to take two weeks off, they got to suck it up and drive on. Do you know what I'm saying?

Moderator: [moderator nods head that he understands] And do you agree, do all three of you agree though that during RAP week that the three events that you [pointing to #2] mentioned are, what were those events?

#2: 5-mile run, and the foot march.

Moderator: Foot march, do you all agree these are the most stressful events for heat injuries?

#4: I think Land Nav [mean land navigation task] is very stressful.

Moderator: Land Nav, OK, We'll add Land Nav, too.

#3: Cause, Yeah, in Land Nav they do a couple of events before they hit Land Nav. Then they do Land Nav and then they go right into some other events, and then they go into the road march. I mean it just breaks you down.

#4: Yeah, I mean the 5-mile run, honestly, yes it is strenuous, but I would think that your Thursday into Friday is the biggest [meaning most stressful] because it is continuous, you got, you go all day. Buddy Run, Malvesti [meaning the Ranger obstacle course], WCT [meaning Water Confidence Test], hand to hand, you go right into Friday morning, zero-two [meaning 0200 in the morning] to the Land Nav retest, RBFT [meaning Ranger Bayonett Fighting Techniques], and you get a little break after, but you get only a 2-hour sleep period between.

Moderator: [interrupts] So, you're thinking that the cumulative effects of that long day is going to start affecting you?

#4: When is your temperature going to drop?

Moderator: [Laughing] I don't know, you tell me.

#4: When you are drinking water, that's the main time, so they're continuously going except for that two-hour period where their core temp can drop and that is it.

Moderator: [Nodding] Right.

#4: The only other thing I would have to say is that I don't feel that I know the accuracy of the actual pill because I didn't have a chance to do a core temp [means a rectal temperature] at the same time. So I couldn't test the product to what our protocol is. That was the only thing. Where if the thermometer said 104 [means 104° F] and my core temp says 104 [he now means the CTM reads 104°F]. That's the only thing.

Moderator: But if it was accurate, if we could prove to you that it was accurate, then would that be fine [referring to the thermometer pill and its CTM unit being accurate, would that be OK for Ranger medics to use]?

#4: Oh yeah, that would be sweet. I mean, it's a good concept. I like the concept, but it's just that our protocol has actually saved [meaning the way they the Ranger medics monitor and treat patients now for heat injuries has saved people's lives]. We've done cadre, and we've done students. We know our protocol works. So if I could have, I would have done a rectal temp and at the same time done a core temp on the thing [referring to using the CTM]. I just didn't have the opportunity, in hand, cause we only had one in hand [referring to that fact Ranger medics only had one CTM unit to use and that the medics that were using the CTM device were not those applying any treatment, therefore they were not obtaining rectal temperatures at the same time that they were obtaining a core temperature with the CTM unit]. At least not around here.

Moderator: Anything you guys want to add [referring to #s 2 and 3] on product features? Good points, bad points, or anything else? Cover that?

[Both #2 and #3 nod their heads no to adding anything else and nod their heads yes that we covered the good and bad points of the product.]

Moderator: Now this question, I don't know if you all will know the answer to it, but give it your best shot. If you had to buy this product, if you had to buy it for the Ranger Training Brigade, how much should a pill cost and how much should a monitor cost to make it reasonable? What are the maximum prices that you know, you guys could afford, assuming it [referring to the CTM pill and monitoring system] met all the needs that you know, we've been talking about?

#2: It depends on the manufacturing that one thing.

Moderator: Assume that you know, assume that [#3 interrupts].

#3: I think the pill should be, the monitor obviously be, I don't know what the going price is, but I think the monitor, just like any of our equipment, should be reasonably priced. And I would buy it, I don't know how much.

Moderator: Are we talking like 100 dollars or could it be 1000 dollars?

#3: I think if the monitor, if it, 100 dollars and the pill [pauses].

Moderator: What is the maximum it could be? Because it is going to be more [meaning that the monitor is going to cost more than 100 dollars]. Could it be 250 dollars?

#3: We have pulse oximeters that are about 250 dollars, so that seems reasonable, but the pill, the pill itself should be less than 10 dollars. I mean, it is hard for the unit that spends 19 cents on a met, I mean a plastic cover that can go over a rectal thermometer, compared to, to pay, I mean, it has to be a reasonable price that, where we can sell it to our unit. I mean [interrupted by #2].

#2: Because if it is not [meaning the CTM and pill being reasonably priced], there is no sense in buying it.

#3: It's a budget issue, that's what it is.

#2: Yeah, right.

#3: And trying to plan these supplies around a Ranger class, we only have so much money.

Moderator: Right.

#3: I can buy 300 plastic covers compared to 3 pills. It's not reasonable [meaning the current price of approximately \$50/pill]. If it was under 10 dollars, I think we could sell it to our General.

Moderator: [looking at #2] How about you? Same general price range?

#2: Yes, Yep.

Moderator: [turning to #4] You?

#4: Yes [nodding head yes].

Moderator: So you agree **[looking at #4]? [#4 nods his head yes.]** So everyone agrees on the same general price range, 10 dollars max. OK.

#4: For the pill.

Moderator: For the pill.

#2: Because they're [referring to the Ranger Training Brigade] will have to purchase a lot of pills.

Moderator: I heard from somebody that for the device itself **[meaning the CTM unit]**, a max of 500 to 750 dollars.

#4: 250 to 500 [dollars].

Moderator: 250 to 500 dollars.

#4: Yes.

#3: 250 to 500 [dollars].

#2: 250 to 500 [dollars].

Moderator: 250 to 500 dollars, OK, great. What other features beyond the thermometer pill would you like this product to have, to do? Let's say it could do anything?

#2: Tell if a Soldier is dehydrated or not.

Moderator: OK.

#3: Well, if it could, well [pauses].

Moderator: We are looking for extensions to this product, to make this product better.

#4: Baseline vitals.

#2: Yeah, baseline vitals.

Moderator: What are they? Heartbeat?

#3: I think, I don't know if there is a way, maybe there is, but respirations, obviously your core temp, pulse rate.

#4: Oxygen in your blood.

#3: Maybe a blood pressure.

Moderator: Blood pressure?

#3: Any other vitals **[looks at #2]**? Maybe if a guy's glucose level is low, that would be good, too.

#4: Actually where they're at?

Moderator: You mean geo-location?

#4: We can be sitting at Land Nav now, they can be taking pills, but we could be saving money [means if we don't know where they are, even with a high temperature, medics wouldn't be able to do anything about it if they don't know where these patients are].

#3: So you have a guy started their training event at this time with these vital signs and this glucose level and here he is 3 hours later, obviously something is not right **[meaning if the medics observed abnormal vital signs]**. That would be, just core temp itself is good, but with those other things, that would be **[pauses]**.

Moderator: Excellent?

#3: Yeah.

Moderator: Is there, do you see any value to, instead of having a monitor, all that technology being built into a PDA [means a personal digital assistant]? Do you use PDAs at all?

#2: Yes.

Moderator: [points to #2] You do?

#2: Yes.

Moderator: Could you see, could you see this being useful in a PDA, or is it, the way it is now, good enough?

#2: Well, the Army itself is going to hand-held computers, so it could be [pauses].

Moderator: So you think it would be useful to put it on a PDA?

#2: Yes.

Moderator: [turns to #3] How about you?

#3: I think so. It could adapt to our other technologies that we are used to. Our computers and stuff. With that PDA we can transfer data onto our laptops and things.

#2: Yeah.

#3: So anything, you know, so we don't have to, so anything that can accomplish the same mission, anything where we don't need a separate device to collect the data would be good **[#4 nodding his head]**.

Moderator: You agree [looking at #4]?

#4: Yes.

Moderator: What other military groups do you think would benefit from this technology besides RTB?

#2: Deployed Soldiers.

Moderator: So like in Iraq?

#2: Yeah. All deployed Soldiers.

Moderator: So even on a field mission [meaning training in the field]?

#2: Yeah, because whenever you are away from garrison, you're still at risk.

Moderator: OK.

#3: I think all the military service in general. All of us have our specialties, but I think any one of us as we go about our daily jobs, obviously admin **[meaning administration personnel]** won't, but anything to do with combat arms, Special Operations stuff, training events, many, many units will use this.

Moderator: You anticipated my next question, are there any groups that don't need it? I'll get with you **[turns to #4]** and you **[points to #2]**, and I'll start with you **[looks and points to #2]**.

#2: Non-deployable, non-training units. They wouldn't benefit from it because they're not out in the woods and stuff.

Moderator: [meaning like] People working in offices?

#2 and #3: Yes, yes.

#4: Anybody like in a hospital, they don't need it. I mean, if you're not in a combat MOS [Military Occupational Specialty job classification] or slash or can be attached to where you can go out in actual combat, you don't need it.

#2: The reason of it is, is if you are in a confined controlled environment, you know you basically are able to get treatment [meaning medical treatment for heat injuries, etc.]. This is for Soldiers who are going above and beyond, like Ranger students who are exerting themselves.

Moderator: Who do you think in the military besides RTB would benefit from it **[turning to #4]**?

#4: Any combat element. I agree with going oversees, I think that everybody in the military should be taught and told about the process, because you never know when you are going to get pulled [meaning selected to deploy to a combat environment]. That's the one thing about the military, you never know when you are going to get orders to go somewhere. So even a dentist [means even a dentist in the military should know about this technology, because while it may seem like a dentist might not be given orders, you never know]. So if he knows about it, he can help with the whole thing, too. I mean the SF [means Special Forces Soldiers might be another group that could benefit from this technology].

Moderator: Did you think using the device was relatively straight-forward?

#4: Yeah.

#3: Yes.

#2: Just follow the directions.

Moderator: How about civilian uses for this technology? Any groups, and if you think so **[#4 interrupts]**?

#4: Firefighters, police officers.

#2: Government agencies, DEA [Drug Enforcement Agency], ATF [Alcohol, Tobacco, and Firearms], athletes.

#3: I think sports also.

Moderator: Sports teams?

#3: Sports teams, these types of things. Maybe the medical guy who handles these guys [meaning the medical personnel, such as the trainer who handles the athletes on the team], monitor these guys. I mean, maybe that is too far-fetched.

Moderator: No, no.

#3: You monitor a player's condition and obviously his vital signs are going down and something is going on [meaning his vital signs are getting worse as a game or other athletic event proceeds]. He's fatigued, dehydrated, and you can pull him out [meaning take the athlete out of the game] earlier instead of pushing to the brink.

Moderator: What athletes did you say [points to #3]?

#2: Football players, runners, marathoners, cyclists, triathlons [means triathletes].

Moderator: [turning to #4] And, civilian uses for you.

#4: I said firefighters.

Moderator: Oh yeah, where's my head?

#4: Firefighters, they are always in the damn heat anyways, so where can they go?

#3: And, they have all their gear on, too.

Moderator: Any overall general improvements of the product besides what we've talked about? We talked about extensions of the product. We talked about measuring from farther away. Anything else?

#4: Yeah, can it do the same in the cold weather?

Moderator: Should be able to, but that is one thing that we need to verify to make sure it can.

#4: Because if it can, that is a big plus here.

#3: And, like I said before, if we have this as a remote system that could feed information to a base system, that would be awesome.

#4: Even if it was setup like a little minicomputer in our FLA [ambulance] and what we shoot [meaning taking of a core temperature by pointing the CTM at a patient], then if it gets put [makes typing motion with hands] in there [meaning in the computer].

Moderator: And this is getting a little off of the product itself a little bit, but we're a medical institute [meaning USARIEM], and we deal with technology and informationare there any other problems you guys have as medics that we could address as trying to get a product in your hands? As an example, we used some of those GPS units out there, and is there anything we could help you with? With the product, or information, we've put together water tables [meaning water consumption tables based on ambient conditions, work rates, and clothing worn] in the past. So you can, you think of things like that for a problem out there that our group could help you guys with?

#3: I think the GPS system is awesome. Combined with like a remote system [meaning a remote medical monitoring system like he described above]. Several times with units you have platoons and squads spread out all over the battlefield. Let's say, or even in this one [meaning Ranger training at RTB], you have them spread out all over the training area. If you identify on this GPS system where this guy is, what's wrong with him, and it will cut down [meaning it will cut down on time to get to and treat the patient], because a lot of times we get a patient, and we'll get the grid [meaning geo-location coordinates] to where they are, and it's pitch black dark, and it takes us a few minutes to get over there, actually find the guy and which flow ground he is actually in. And the road often doesn't exactly go to him a lot of times, and you have to get out [out of the ambulance] and search for him. If we knew where he exactly was, it would cut down on treatment times probably about half.

Moderator: Good **[pointing to #2]**. Anything you can think of that we could help you guys with?

#2: I think we covered it.

#4: I think we did, a computer system.

#3: Combine with the vitals on it, that will give you a picture of what's wrong with this guy before we even get to him, so you already know this is what I have to do, these are the things I'm going to do. Plan out your patient care.

#4: Develop a pill that can help you retain water. I know they have ones that make you disperse it. What about ones that help you retain it?

Moderator: OK. So now what I'm going to do now is summarize. Just talk real briefly. So you guys tell me if I got everything correctly. And if I didn't, straighten me out. Basically, you are assessing heat injuries now using the rectal thermometer. You go out to the field, you bring them **[meaning the patient]** to the ambulance, and you put ice sheets on them to cool them down. That's how you treat them. You think a device

like this [meaning the CTM and thermometer pill] would be good, and you think, for the most part, this particular device was a good thing. You thought it would be nice to be able to point the device at the guy [meaning to obtain a core temperature from farther away] and that could be one improvement. You also thought that if it could get other vital signs such as heart rate, or glucose, blood pressure, that would be an improvement and also an extension of the product. In general, you thought the maximum cost of the product could go from \$250 to a max of \$750. The cost of the pills should be very cheap. I actually didn't get a price point on a pill [looks at #4]?

#4: Less than 10 dollars [moderator looks at #3].

#3: Less than 10 dollars.

Moderator: Less than 10 dollars [moderator looks at #2].

#2: Less than 10 dollars.

Moderator: Less than 10 dollars, everyone agrees. Extensions of the product would be sending it [meaning medical information] back [meaning to the Battalion Aid Station] so you know where they are [meaning the patients geo-location in the field and their medical condition]. Also, factoring in a GPS system would be good. You agreed getting it [meaning the software and hardware technology of the VitalSense® monitor] on a PDA would be good. Less complicated would make it more convenient. Other groups that would benefit from it would be especially those deployed oversees of just even in field training ones. People that wouldn't need it are people in hospitals or in buildings, admin people. Civilian uses would be sports, sports teams, primarily firefighters, policeman. And that pretty much is what I got out of this. Do you guys pretty much agree with this summary? [All nod yes.] OK, well, this went great. Thank you very much. I really appreciated it. For me, this went great. I mean your info was really helpful, and I really appreciated it. Thank you very much.

[Moderator thanks everyone and shakes their hands.]

FOCUS GROUP SESSION 3

Moderator: Do you have any problems assessing core temperature?

#1: It is difficult at times because of having to get their clothes off. Often it takes a lot of time.

Moderator: How do you get their clothes off?

#1: If they are unconscious we cut them off. If they are conscious we have them help us undress them.

Moderator: How do you currently assess a Soldier's core temperature?

#1: Put them on the truck. Have them stripped down, and then get a rectal temperature.

Moderator: How do you assess core temperature in the field if they are fully clothed with personal protective equipment such as them being in MOPP?

#1: If they are in MOPP and it is an NBC environment, we would not touch them. If we could be sure that they were not exposed, then the treatment would be the same. Strip them down and get a rectal temperature along with other vitals. If they were in MOPP and went through the decontamination process we could then treat them, but if a guy was suffering from a heat injury in an NBC environment, we wouldn't treat him.

Moderator: Are there certain at-risk individuals?

#1: Yes, those with previous hot and cold weather injuries would be more susceptible.

Moderator: Both previous hot and cold weather injuries would be more susceptible to heat injuries here at the RTB?

#1: Yes, both.

Moderator: How are at-risk individuals managed medically during training?

#1: We mark them with a piece of tape on their uniform. That way, we **[referring to the medics]** can keep an eye on them.

Moderator: In general, what do you think of a thermometer pill? Just the general concept, and not this particular product.

#1: I think it is good and could be useful.

Moderator: What do you think about this particular product?

#1: It is a good idea. Most of the time it seems effective. But I sometimes waited for a reading for as long as 3 to 4 minutes before I got a reading. That is way too long. Other times I didn't get a reading at all. I could have cut their clothes off, and gotten a reading [meaning he could have gotten a reading with a rectal thermometer as is done presently]. The goal is to get them back in training without taking too much time. This pill technology didn't meet that [means that objective].

Moderator: So what are the thermometer pill and its reader's least attractive features?

#1: It took too long. The light on the unit was bad. That is, it didn't work too well. You need to have the light to stay on. The back light on the screen, even when it was on, was way too faint. You need to be too close to the Soldier to get a reading even when you get one.

Moderator: What are the most attractive features?

#1: You don't have to cut a guy's clothes off. And if it could be quicker, that is, if you could make the device quicker to get a temperature, then it could be really good. If that can't be done, that is to make it quicker, I don't really see any use of it for us.

Moderator: Suppose we could fix it, fix the things you didn't like. Would you use it if it were available to you?

#1: Yes, I would use it.

Moderator: What is the maximum you think the CTM unit should cost?

#1: 500 dollars

Moderator: What do you think is a reasonable amount for the Army to pay for each pill?

#1: It should be a dollar or less. Maybe a maximum of \$5 per pill.

Moderator: Are there any other features you would like this product to have that it doesn't have presently?

#1: To get all the vitals at a click of a button. You know, blood pressure, temperature, heart rate, respiration.

Moderator: Is there any value to having the thermometer pill CTM be part of a PDA?

#1: It is good by itself if it could do all the vitals. As it is though, it is a little cumbersome just for temperature and should be part of another piece of equipment.

Moderator: Would the CTM benefit other groups besides the RTB?

#1: SF. Both schools and SF teams. Also, it would be useful for Basic Training.

Moderator: Any groups of medical personnel that would not need this technology?

#1: Units that don't do anything. I mean, like those that have normal office jobs. Maybe mechanics or other groups that are not putting their bodies under duress.

Moderator: Are there any civilian uses for this technology?

#1: No, not that I can think of.

Moderator: Are there any other improvements that are needed?

#1: No. [Volunteer seems to be tired of questions, moderator decided to end interview session at this point.]

Moderator: Thank you very much for your helpful feedback. I appreciate this very much. Thanks again for taking the time to give me your opinions.